REMARKS/ARGUMENTS

Summary of Amendments, support, status of claims

The independent claims are 1, 16, 21and 22. All have been limited to the use of polyclonal antibodies. The limitation is supported at page 5, lines 15-16, for example.

Claim 1 has been amended to recite:

> "a mixture of a plurality of proteonic cancer markers from different cancer cell lines, said mixture containing markers identified and markers not yet identified,"

Support for the limitation "a plurality of proteonic cancer markers" is found in original claim 15, for example, which recites "antibodies made against a plurality of proteonic cancer markers". Fair support for the limitation "said mixture containing markers identified and markers not yet identified" is found in the specification at page 7, lines 25-26, which reads: "Each type of cancer cell has it's own identified and not yet identified cancer markers."

Claim 4 has been amended to recite:

> "a) providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and markers not yet identified,
>
> b) forming antibodies against the mixture "

The added limitation is supported by page 4, lines 11-13 of the specification as filed, which reads:

> "The saliva sample is then brought together with a reagent containing antibodies made against a mixture of plurality of proteonic cancer markers from different types of cancer cells to form an assay sample."

together with page 7, lines 25-26 as noted above.

Claim 16 has been amended to recite:

> c) bringing the saliva sample together with a reagent containing polyclonal antibodies made against a plurality of proteonic cancer markers, some identified and others not yet identified, from different types of cancer cells to form an assay sample;"

Fair support for the limitation "some identified and others not yet identified" is at page 7, lines 25-26 of the specification, quoted above.

Claim 21 has been amended to recite:

> "each reagent containing a separate slate of polyclonal antibodies made against proteonic cancer markers identified and markers not yet identified from different types of cancer cells, one type of cancer cells being used to form each slate of antibodies, to form a plurality of assay samples;"

Fair support for the limitation "proteonic cancer markers identified and markers not yet identified" is at page 7, lines 25-26 of the specification, quoted above.

Claim 22 has been amended to recite:

> "c) bringing the first saliva sample together with a reagent containing polyclonal antibodies made against ~~at least one proteonic cancer marker~~ identified and not yet identified proteonic cancer markers made from a single cancer cell line to form a first assay sample,"

Fair support for the limitation "polyclonal antibodies made against identified and not yet identified proteonic cancer markers" is at page 7, lines 25-26 of the specification, quoted above.

Claims 1, 4, 6, 8, 13 ,16, 18, 20, 21 and 22 have been amended. Claims 5 and 7 have been canceled. Claims 1-4, 6, and 8-23 remain pending.

Rejections under 35 USC 112

of claims 4-10, 13-14 under first paragraph

Claims 4-10, 13-14 stand rejected under 35 USC 112, first paragraph, on the basis that the specification does not contain a written description of the claimed invention. The basis of the rejection is the recitation, in claim 4, of "providing a plurality of colonies of cancer cells, each colony being of a different cancer cell line," which is said to have no clear support in the specification and the claims as originally filed.

The rejection is traversed but is submitted to be obviated by amendment to claim 4, which now recites:

"a) providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and markers not yet identified,

b) forming antibodies against the mixture "

supported as pointed out above, and by changing the dependencies of claims 6, 8 and 13 to depend from claim 1. Reconsideration and withdrawal of the rejection is requested.

of claims 18-20 under first paragraph

Claims 18-20 stand rejected under 35 USC 112, first paragraph, on the basis that the specification does not contain a written description of the claimed invention. The basis of the rejection is the recitation, in claim 18, of "proteonic cancer cell markers made from at least two cell lines," which is said to have no clear support in the specification and the claims as originally filed.

The rejection is traversed but is submitted to be obviated by amendment to claim 18, which now recites:

"proteonic cancer cell markers made from ~~at least two cell lines selected from~~ the

group consisting of a breast cancer cell line, a lung cancer cell line, a stomach cancer cell line, a liver cancer cell line, a colon cancer cell line, an ovarian cancer cell line, a cervical cancer cell line, a mouth/pharynx cancer cell line, a skin cancer cell line, a pancreatic cancer cell line, a testes cancer cell line, a brain tumor cell line, and a prostate cancer cell line ."

The amended language is submitted to be fairly supported by page 5, lines 9-13, which reads:

"For example, the cell line can be selected from the group consisting of a breast cancer cell line, a lung cancer cell line, a stomach cancer cell line, a liver cancer cell line, a colon cancer cell line, an ovarian cancer cell line, a cervical cancer cell line, a mouth/pharynx cancer cell line, a skin cancer cell line, a pancreatic cancer cell line, a testes cancer cell line, a brain tumor cell line, and a prostate cancer cell line."

Reconsideration and withdrawal of the rejection is requested.

Prior art rejections

The cited art

Streckfus et al, US 6,294,349, issued September 25, 2001, assays for three known specific biomarkers, c-erbB-2, CA 15-3, and p53 for breast cancer in saliva (abstract). All assays disclosed by Streckfus et al employ single-antibody kits specific for the known antigen being tested against. In example 6, two single-antibody kits specific for the same known antigen (CD) were simultaneously employed.

El Deiry et al (Cell Death and Differentiation, 2001, 8:1066-1075) teaches that p53 is a

known marker that is common in a wide variety of cancer cell types

Links et al (Expert Reviews in Molecular Medicine, 1999: 1-21) teaches that c-erb-2 is a known marker overexpressed in some breast, ovarian and colorectal cancers

Harlow et al (Antibodies, a Laboratory Manual, Cold Spring Harbor Laboratory Press, 1988, p. 142) teaches that monoclonal antibodies are often more time-consuming and costly to prepare than polyclonal antibodies, and they are not necessarily the best choice for certain immunochemical techniques. Harlow doesn't teach to look for unknown markers to screen for cancer.

Cruse et al (illustrated Dictionary of Immunology, CRC Press, New York, page 241, 1995) teaches that polyclonal antibodies are mixtures of antibodies that bind to different epitopes of an antigen. Cruse doesn't teach to form antibodies against markers identified and markers not yet identified to screen for cancer.

Herr et al., US 5,047,508, September 10, 1991 teaches a conventional ELISA assay wherein the sample is coated on the plate prior to being brought together with a monoclonal antibody reagent to detect sperm (col 4, lines 20-44). Herr doesn't teach use of a polyclonal agent to detect cancer markers identified or not yet identified.

Diamond, US 4,690,905, September 1, 1987 teaches coating the plates with serum sample prior to bring the sample together with monoclonal antibody containing reagent. (col. 9, lines 16-34). Diamond doesn't teach coating the plate with saliva sample or use of polyclonal agent formed against cancer markers identified or not yet identified.

Rejections under 35 USC 103

of claims 1-3, 11-12, 15-19, 21-23

Claims 1-3, 11-12, 15-19, 21-23 stand rejected under 35 USC 103(a) as being unpatentable over Streckfus et al, US 6,294,349, issued September 25, 2001 in view of El Deiry et al (Cell Death and Differentiation, 2001, 8:1066-1075) and Links et al (Expert Reviews in Molecular Medicine, 1999: 1-21) "essentially for the reasons previously set forth in the paper mailed March 8, 2007, Section 5, P. 5-8". Reference is assumed to be to the office action dated November 16, 2006, which contains a 103 rejection in section 5, pages 5-8, there being no paper dated March 8, 2007 in the undersigned's file or indicated on PAIR.

Claims 1, 2-3, 11-12, and 15 patentably distinguish the references by the recitation of

> "a reagent containing polyclonal antibodies made against a mixture of a plurality of proteonic cancer markers from different cancer cell lines, said mixture containing markers identified and markers not yet identified".

The cited references employ either a reagent formed from monoclonal antibodies or a reagent formed from polyclonal antibodies made against a known antigen.

Claims 16 and 17-19 patentably distinguish the references by the recitation of

> " a reagent containing polyclonal antibodies made against a plurality of proteonic cancer markers, some identified and others not yet identified, from different types of cancer cells"

The cited references employ either a reagent formed from monoclonal antibodies or a reagent formed from polyclonal antibodies made against a known antigen.

Claim 21 patentably distinguishes the references by the recitation of

> "each reagent containing a separate slate of polyclonal antibodies made against

proteonic cancer markers identified and markers not yet identified from different types of cancer cells, one type of cancer cells being used to form each slate of antibodies, to form a plurality of assay samples;"

The cited references employ either a reagent formed from monoclonal antibodies or a reagent formed from polyclonal antibodies made against a known antigen.

Claims 22-23 distinguishes the combination of references by the recitation of:

"c) bringing the first saliva sample together with a reagent containing polyclonal antibodies made against ~~at least one proteonic cancer marker~~ identified and not yet identified proteonic cancer markers made from a single cancer cell line to form a first assay sample,"

The cited references employ either a reagent formed from monoclonal antibodies or a reagent formed from polyclonal antibodies made against a known antigen.

The combined references fail to suggest cancer screening by using polyclonal agent made against cancer markers from different cell lines containing markers identified and markers not yet identified. Reconsideration and withdrawal of the 35 USC 103 rejection of these claims is requested.

of claims 4-10, 13-14

Claims 4-10, 13-14 stand rejected under 35 USC 103(a) as being unpatentable over Streckfus et al in view of El Deiry et al and Links et al further in view of Harlow et al (Antibodies, a Laboratory Manual, Cold Spring harbor Laboratory Press, 1988, p. 142) and Cruse et al (illustrated Dictionary of Immunology, CRC Press, New York, page 241, 1995) essentially for the reasons previously set forth in the paper mailed March 8, 2007, Section 6, pgs 8-10. Reference is assumed to be to the office action dated November 16, 2006, which contains a 103 rejection in section 6, pages 8-10, there being no paper dated

March 8, 2007 in the undersigned's file or indicated on PAIR.

This rejection is traversed but is obviated by the present amendment. Claims 5 and 7 have been canceled. Claims 6, 8-10, and 13-14 now depend from claim 1.

Claim 4 as amended distinguishes the combined references by the recitation of:

> "a) providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and markers not yet identified,
>
> b) forming polyclonal antibodies against the mixture; and
>
> c) forming the reagent from said polyclonal antibodies."

Claims 6, 8-10 and 13-14 distinguish the combined references by the recitation in claim 1 of:

> "a reagent containing polyclonal antibodies made against a mixture of a plurality of proteonic cancer markers from different cancer cell lines, said mixture containing markers identified and markers not yet identified".

The cited references employ either a reagent formed from monoclonal antibodies or a reagent formed from polyclonal antibodies made against a known antigen. There is no teaching in the combined references of use of a reagent containing polyclonal antibodies formed as recited.

Reconsideration and withdrawal of this rejection is requested.

of claims 1, 2, 3, 17, 18, 19, 22-23

Claims 1, 2, 3, 17, 18, 19, 22-23stand rejected under 35 USC 103 as being unpatentable over Streckfus et al in view of El Deiry et al and Links et al essentially for the reasons

previously set forth in the paper mailed November 16, 2006, Section 5, pages 5-8 and further in view of Herr et al., US 5,047,508, September 10, 1991 or Diamond, US 4,690,905, September 1, 1987.

Claims 1, 2 and 3 distinguish the combined references by the recitation in claim 1 of

> "a reagent containing polyclonal antibodies made against a mixture of a plurality of proteonic cancer markers from different cancer cell lines, said mixture containing markers identified and markers not yet identified"

The cited references employ either a reagent formed from monoclonal antibodies or a reagent formed from polyclonal antibodies made against a known antigen.

Claims 17, 18, 19 distinguish the combined references by the recitation in claim 16 of

> "bringing the saliva sample together with a reagent containing polyclonal antibodies made against a plurality of proteonic cancer markers, some identified and others not yet identified, from different types of cancer cells to form an assay sample"

The cited references employ either a reagent formed from monoclonal antibodies or a reagent formed from polyclonal antibodies made against a known antigen.

Claims 22-23 distinguish the combined references by the recitation in claim 22 of

> "c) bringing the first saliva sample together with a reagent containing polyclonal antibodies made against ~~at least one proteonic cancer marker~~ identified and not yet identified proteonic cancer markers made from a single cancer cell line to form a first assay sample,"

The cited references employ either a reagent formed from monoclonal antibodies or a reagent formed from polyclonal antibodies made against a known antigen. There is no teaching in the combined references of use of a reagent containing polyclonal antibodies

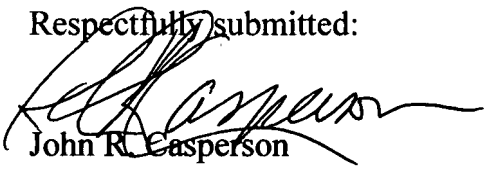
formed as recited in the rejected claims.

Reconsideration and withdrawal of the rejection is requested.

Conclusion

In view of the foregoing, reconsideration and withdrawal of all grounds of rejection and early notice of allowance is respectfully solicited.

Respectfully submitted:



John R. Casperson
Reg. No. 28,198

Please mail correspondence to:

John R. Casperson
PO Box 2174
Friendswood, Texas 77549

Tel. No. 281-482-2961